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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,699	06/14/2002	Ikuo Nishimoto	082376-000000US	2315
7590 10/18/2007 Joe Liebeschuetz Townsend & Townsend & Crew 8th Floor Two Embarcadero Center San Francisco, CA 94111-3834			EXAMINER VOGEL, NANCY S	
			ART UNIT 1636	PAPER NUMBER
			MAIL DATE 10/18/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/088,699

Applicant(s)

NISHIMOTO, IKUO

Examiner

Nancy T. Vogel

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-4, 18, 20 and 22 is/are pending in the application.
- 4a) Of the above claim(s) 3 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2, 18, 20 and 22 is/are rejected.
- 7) ☒ Claim(s) 4 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>8/6/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/6/07 has been entered.

Claims 2-4, 18, 20, 22 are pending in the case. Claim 3 is withdrawn.

Receipt of the Information Disclosure Statement on 8/6/07 is acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 18, 20, 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is maintained essentially for the reasons made of record in the previous Office action mailed 3/2/07, but limited to the recitation in claim 2 of the phrase "detecting a suppressive effect on Alzheimer's Disease due to the expression of a nucleic acid of the library".

The claims are drawn to methods of screening for a suppressor gene of Alzheimer's Disease, wherein said method comprises the steps of (a) expressing in a population of cells a library of nucleic acids obtained from or synthesized from nucleic acids expressed in a tissue of an organism suffering from a disorder, wherein said tissue is obtained from an organ showing cell death as a pathological feature of the disorder; (b) detecting a suppressive effect on the disorder due to the expression of a nucleic acid of the library; and (c) selecting the nucleic acid having the suppressive effect; thereby identifying a disorder suppressor gene. The claims encompass any suppressive effect. The claims do not provide any information with regard to which suppressive effects would be selected. Thus, the rejected claims comprise a set of methods utilizing cells/nucleic acids/organs that are defined by their function in identifying a nucleic acid "having a suppressive effect on Alzheimer's Disease."

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of a complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, and any combination thereof. The specification describes

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the preparation of a cDNA library from the brain sample of a patient with Alzheimer's disease (AD). The cDNAs were transfected into FII/EcR/V6421I cells, which were then treated with ecdysone for 72 hours, and then plasmids were recovered from the surviving cells (see instant specification at, e.g., page 37, lines 8-36). The specification also describes how sequencing of the clones revealed the sequence for humanin (HN), which was subcloned into the pFLAG vector to yield pHN (see, e.g., Example 3 on pages 38-39). FII cells transfected with pHN were protected from the toxic effects of the familial Alzheimer's disease genes V642I APP, NL-APP, M146L PS-1, and N141I PS-2 (ibid and Figure 5). No description of any other working examples utilizing any other effects are disclosed.

Even if one accepts that the examples described in the specification meet the claim limitations of the rejected claims with regard to structure and function, the examples are only representative of a method showing cell death as a pathological feature of the disorder for which a disorder suppressor gene was identified. The results are not necessarily predictive of the method involving suppression of any other features of Alzheimer's .

Given the very large genus of the term "suppressive effect on Alzheimer's Disease", a disease for which characterization and understanding is limited, it is concluded that the specification has not provided a description of the claims throughout its scope. Therefore, the skilled artisan would have reasonably concluded Applicant was not in possession of the claimed invention for claims 2, 18, 20, 22.

Applicant's arguments filed 8/6/07 have been considered but have not been found convincing.

Applicants have argued that present claims are directed to a method screening for a candidate suppressor gene rather than for a method of treating Alzheimer's Disease, and that the claims do not require that every gene identified ultimately prove to be a useful gene for treating Alzheimer's disease (page 6-7). However, while this is acknowledged, it is maintained that the rejected claims include a step of screening or detecting "a suppressive effect on Alzheimer's Disease", while the claim which is not included in the instant rejection, i.e. claim 4, specifies that the effect which is examined is cell death. Therefore, the rejection is maintained for claims 2, 18, 20 and 22, for which there is no effect specified.

Conclusion

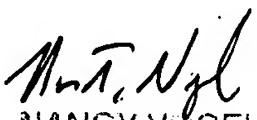
Claim 4 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (571) 272-0780. The examiner can normally be reached on 7:00 - 3:30, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NTV
10/12/07


NANCY VOGEL
PRIMARY EXAMINER